In The United States Patent Office

In re Albert M. FLEISCHNER, Ph.D., "Herbal Composition for Weight Control"	:	Technology Center 1655 Serial No. 10/693,442 Filed 23 October 2003
	:	**APPEAL BRIEF**

TABLE OF AUTHORITIES

CASES

TABLE OF CONTENTS

I. INTRODUCTION

This APPEAL BRIEF is submitted pursuant to the earlier-submitted NOTICE OF APPEAL. Enclosed please find the large-entity fee for filing an appeal brief. This APPEAL BRIEF is filed within two months of the earlier-submitted NOTICE OF APPEAL. No extension of time fee is therefore believed due.

This patent application has been granted Special status. Expedited resolution of this appeal is therefore respectfully requested.

A. Real Party In Interest

The real party in interest is TrimSpa Corporation, a New Jersey corporation.

B. Related Appeals and Interferences

There are no related appeals nor interferences known to appellant, the appellant's legal representative, nor the assignee which may be related to, directly affect nor be directly affected by or have a bearing on the Board's decision in the immediate appeal.

C. Status of Claims

Claims 8 to 16 and 27 stand canceled. Claims 1 to 7, 17 to 26 and 28 to 40 stand twice rejected. Appellant appeals the rejection of all pending claims.

D. Status of Amendments

No amendment has been filed subsequent to a final rejection.

E. Summary of Claimed Subject Matter

Hoodia gordonii is a cactus. *See* SPECIFICATION at page 3, line 3. The prior art teaches that 3-0-[-ß-D-thevetopyrano-sylcymaropyranosyl]-12ß-0-tigloyloxy-14ß-hydroxy-14-pregn-50-en-20-one, a compound naturally present in *Hoodia gordonii*, temporarily suppresses hunger, then stimulates hunger, causing a net increase in body weight. *Id*. at page 3, line 8 to page 4, line 21. That compound thus appears suitable for investigation as, *e.g*., a body-building supplement. In contrast, the Inventor has found that *Hoodia gordonii* can be used to reduce excess body weight and maintain a healthy lower body weight.

Independent claim number 1 is drawn to a method of body weight reduction comprising administering a body weight reducing amount of *hoodia gordonii* at least once every 48 hours, for about 45 days. *Id*. at page 5, line 10 *et seq*.

Dependent claim number 2 is drawn to a method of body weight reduction comprising administering *hoodia gordonii* at least three times every 24 hours, for about 45 days. *Id*. at page 6, line 3 *et seq*.

Dependent claim number 3 is drawn to a method of body weight reduction comprising administering *hoodia gordonii* and a second compound

selected from the group consisting of a stimulant and glucosamine, for about 45 days. *Id*. at page 6, line 7 *et seq*.

Independent claim 19 is drawn to a composition of matter for body weight reduction, comprising *hoodia gordonii* and a second compound (a stimulant and/or glucosamine). *Id*. at, *e.g*., page 31, lines 18-22.

Independent claim 35 is drawn to a method of body weight reduction comprising administering *hoodia gordonii* in an amount sufficient to suppress the appetite, said administration repeated a plurality of times, each one of said times occurring before the *hoodia gordonii* causes an appetite stimulating effect. *Id*. at page 5, line 22 *et seq*.

F. Grounds of Rejection to be Reviewed on Appeal

The grounds for rejection presented on appeal are as follows:

i. Whether the OFFICE ACTION states a *prima facie* case of any of claims 1 to 7, 17 to 26 and 28 to 40 failing to comply with the "written description" requirement of Section 112, first paragraph?

ii. Whether the OFFICE ACTION states a *prima facie* case of any of claims 1 to 7, 17 to 26 and 28 to 40 failing to comply with the enablement requirement of Section 112, first paragraph?

iii. Whether the OFFICE ACTION states a *prima facie* case of any of claims 1 to 7, 17 to 26 and 28 to 40 being obvious under Section 103?

G. Argument

Applicant respectfully believes the application presents four groups of claims, each group independently patentable *viz* the art of record:

Claim 1 - *Hoodia gordonii* for weight control

Claim 2 – *Hoodia gordonii* Intensive administration regimen

Claims 3, 19 and 37 – *Hoodia gordonii* combined with glucosamine or a stimulant.

Claim 35 – An administration regimen for *Hoodia gordonii*.

The claim groups argued separately from claim 1 are placed under sub-headings including the relevant claim number.

II. THE OFFICE ACTION FAILS TO STATE A *PRIMA FACIE* CASE OF NON-COMPLIANCE OF ANY OF CLAIMS 1 TO 7, 17 TO 26 AND 28 TO 40 WITH 35 U.S.C. § 112, FIRST PARAGRAPH

A. The Original Disclosure Provides Adequate Written Description For Dependent Claims 23-26 And 28-34

The OFFICE ACTION alleges that the original disclosure fails to provide an adequate written description supporting dependent claims 23-26 and 28-34. The OFFICE ACTION, however, fails to state a *prima facie* case.

1. The Examiner Must Provide Evidence Showing That The Disclosure Fails To Support The Claimed Invention

To satisfy the written description requirement, the original disclosure must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *See Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319 (Fed. Cir., 2003). The original disclosure includes both the specification and the claims originally filed. *E.g., In re Benno*, 768 F.2d 1340 (Fed. Cir. 1985); *In re Koller*, 613 F.2d 819 (C.C.P.A., 1980). Thus, most of the "written description" caselaw addresses whether the disclosure as originally filed provides adequate support for amendments to the claims or the specification. *See e.g., In re Lukach*, 442 F.2d 967 (C.C.P.A., 1971); *Martin v. Mayer*, 823 F.2d 500, 503 (Fed. Cir. 1987).

In contrast, there is a strong presumption that an adequate "written description of the claimed invention is present in the disclosure as filed. *See In re Wertheim*, 541 F.2d 257, 263 (C.C.P.A., 1976). Thus, the Patent Office bears the burden of presenting evidence showing that the original disclosure fails to show possession of the claimed invention. *Id.*

2. The Examiner Fails To Provide Evidence That The Disclosure Does Not Support Claims 23-26 And 28-34

In the immediate case, independent claim 19 covers " A composition of matter for body weight reduction, comprising a body weight reducing amount of *hoodia gordonii* together with a second compound selected from the group consisting of a stimulant and glucosamine." In contrast, claims 23-26 and 28-34 depend from claim 19, and specify particular amounts of stimulant or glucosamine.

The Examiner acknowledges that claim 19 is part of the original disclosure, and therefore is adequately supported by it. The Examiner, however, argues that dependent claims 23-26 and 28-34 impermissibly "broaden" the concept of independent claim 19:

> [claims 23-26 and 28-34] broaden the concept of the originally disclosed / claimed invention – i.e., the original disclosure and claims were limited to disclosed effective amounts (e.g., particular ranges) of one or more of the ingredients recited. … the original specification including the original claims do not support the concept of any and all undefined amount(s) of the recited ingredients.

Applicant respectfully disagrees, for two reasons.

First, dependent claims cannot "broaden" an independent claim as a matter of law.

Second, the "concept of the originally disclosed claimed invention" was not "limited to disclosed effective amounts (e.g., particular ranges)" of

stimulant and/or glucosamine. To the contrary, claim 19 uses the transitional phrase "comprising." In so doing, claim 19 provides a written description of a composition including *hoodia gordonii* and a stimulant and/or glucosamine, alone or together with any other ingredient(s), regardless of how much stimulant, regardless of how much glucosamine, and regardless of how much other ingredient(s) is present.[1]

The disputed claims depend from claim 19, and merely add to the basic invention of claim 19 additional limitations. As dependent claims, the disputed claims cannot "broaden the concept of" the invention of claim 19.

B. The OFFICE ACTION Fails To State A *Prima Facie* Case Of Non-Enablement For Claims 1-7, 17-26 and 28-40

The OFFICE ACTION argues that claims 1-7, 17-26 and 28-40 are not deemed enabled without "evidence [] that the claimed biological material (*e.g.*, the required amount of seeds from the instantly claimed plant *Hoodia gordonii*) is

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[1] The transitional phrase "consisting of" excludes any ingredient not specified in the claim. *E.g., Ex parte Gray*, 53 F.2d 520 (C.C.P.A. 1931). In contrast, the transitional phrase "comprising" is open-ended, and allows for additional ingredients not expressly recited in the claim. *E.g.*, *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir., 1997); *Moleculon Res. Corp. v. CBS, Inc.*, 793 F.2d 1261 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686 (C.C.P.A., 1981); *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I., 1948) (the transitional phrase "comprising" leaves "the claim open for the inclusion of ingredients even in major amounts").

known and readily available." The OFFICE ACTION thus alleges that the correct legal test is that Hoodia gordonii be both known and readily available.

The OFFICE ACTION fails to state a *prima facie* case of non-enablement for several reasons.

First, the OFFICE ACTION fails to address the claimed invention. The OFFICE ACTION demands evidence that "the claimed biological material" is known and available. The claims are not, however, drawn to "biological material." Rather, the claims are drawn to methods for using a plant, and compositions including that plant.

Second, the administrative agency record shows that *Hoodia gordonii* is "known." Evidence showing that *Hoodia gordonii* is known includes, for example, the prior art which the Examiner relies on to argue that the claimed invention is obvious. Put another way, the Examiner's allegation that *Hoodia gordonii* is known in the art for purposes of Section 103, contradicts his allegation that it is unknown for purposes of Section 112, first paragraph.

Third, the agency record shows that *Hoodia gordonii* is readily available. Applicant's PETITION TO MAKE EXAMINATION SPECIAL made of record evidence showing that Applicant's TrimSpa® brand *Hoodia gordonii* product is

readily available, as are various competitors' slavish copies of it.[2] Indeed, since the filing of the immediate application, Applicant's TrimSpa® product has enjoyed a singular commercial success; this success has in turn induced widespread copying. *See* INFORMATION DISCLOSURE STATEMENT (7 May 2006) (making of record evidence showing that copies of the Applicant's *Hoodia gordonii* product is now available from, *inter alia,* hoodoba.com, weightlossguide.com, h57.com, hoodithin.com and phenterlean.com.) The factual record before the agency therefore shows that *Hoodia gordonii* is readily available.

The OFFICE ACTION (10 Feb. 2006) argues that "this cactus plant only grows wild in the Kalahari Desert." Assuming that this factual allegation is true,[3] where something "grows wild" is not the applicable legal standard. Rather, the applicable legal standard is whether the disclosure as a whole, read in the context of the knowledge of the art, enables one of skill in the art to practice the claimed invention.

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[2] If imitation be the sincerest form of flattery, these products show it abundantly; the TrimSmart™, TrimClub™ and HoodiaSpa™ products not only copy Applicant's product, but also Applicant's packaging, label graphics and trademarks!

[3] It might not be. The record shows that *Hoodia gordonii* grows wild in the Kalahari Desert. The record, however, fails to show that *Hoodia gordonii* **only** grows in the Kalahari Desert.

In the immediate case, the Examiner does not dispute that one of skill in the art can practice the claimed invention. To the contrary, the agency record shows that since the immediate patent application was published (in December of 2004), numerous parties *are in fact actually practicing the claimed invention* in The United States. *See e.g.*, PETITION TO MAKE EXAMINATION SPECIAL UNDER 37 C.F.R. § 1.17(H) (9 July 2005); INFORMATION DISCLOSURE STATEMENT (7 May 2006); Martina HABECK, *A Succulent Cure To End Obesity*, 7 DRUG DISCOV. TODAY 280 (March 2002) at Figure 1 (photograph of *Hoodia* seedlings being propagated in a greenhouse in Godmanchester, United Kingdom); Albert M. Fleischner, DECLARATION (13 June 2006) at ¶¶ 8-9; Ian B. OLIVER, *Grow Succulents* (2003) (teaching that *Hoodia* cactus may be cultivated outside of the Kalahari desert, that it makes a wonderful container plant and that it looks handsome in terra cotta containers).

The administrative agency record therefore shows that *Hoodia gordonii* is known in the art, and is available both commercially and as a cultivar.

III. THE OFFICE ACTION FAILS TO STATE A *PRIMA FACIE* CASE OF OBVIOUSNESS UNDER 35 U.S.C. 103 FOR ANY OF CLAIMS 1 TO 7, 17 TO 26 AND 28 TO 40

A *prima facie* case of obviousness requires three elements. *In re Vaeck*, 947 F.2d 488 (Fed.Cir. 1991). First, the prior art must teach each element

of the claims at issue. Second, the prior art must teach a reasonable expectation of success. Third, the prior art must suggest modifying the prior art to replicate the claimed invention. In the instant case, the prior art fails to fulfill any of these three elements.

A. The References Relied on By the Examiner

The OFFICE ACTION relies on the following prior art references to show obviousness:

I. Fanie Retief VAN HEERDEN *et al.*, *Pharmaceutical Compositions Having Appetite Suppressant Activity*, U.S. Letters Patent No. 6,376,657, teaches that 3-0-[-ß-D-thevetopyrano-sylcymaropyranosyl]-12ß-0-tigloyloxy-14ß-hydroxy-14-pregn-50-en-20-one, a compound which occurs naturally in *Hoodia gordonii,* causes transient appetite suppression followed by appetite stimulation and a net body weight gain.

II. Martina HABECK, *A Succulent Cure To End Obesity*, 7 DRUG DISCOV. TODAY 280 (March, 2002) teaches that 3-0-[-ß-D-thevetopyrano-sylcymaropyranosyl]-12ß-0-tigloyloxy-14ß-hydroxy-14-pregn-50-en-20-one does not cause weight loss.

III. Anthony BARNETT, *In Africa the Hoodia Cactus Keeps Men Alive*, THE OBSERVER (17 June 2001) teaches that *Hoodia gordonii* causes transient appetite suppression.

IV. Tamar KAHN, *Prickly Dispute Finally Laid To Rest*, BUSINESS DAY (JOHANNESBURG) (22 March 2002) teaches that *Hoodia gordonii* causes transient appetite suppression.

V. Orien Lee TULP *et al., Effect of Hoodia Plant on Food Intake and Body weight In Lean And Obese LA/Ntul//-cp Rats*, 15 FASEB JOURNAL A404 (7 March 2001) teaches that laboratory rats with impaired thermogenesis and sugar metabolism can lose weight when given *Hoodia gordonii*.

These references, alone or combined, fail to establish a *prima facie* case that it would have been obvious to use *Hoodia gordonii* for weight loss in humans.

B. Appetite Suppression Is Not Weight Control

The error in the Examiner's position appears based on a fundamental misunderstanding regarding the relationship between appetite suppression and weight control; while the Examiner equates the two, the art of record – and the Office's own records for other cases in this field – shows that one of skill in the art would recognize that the two concepts are not coterminous. To the contrary, one

of skill in the art would understand that weight loss does not require appetite suppression, and appetite suppression does not of itself cause weight loss.

1. Weight Loss Does Not Require Appetite Suppression

It is possible to cause weight loss without suppressing appetite. This is the clinical result obtained by the use of amphetamines or exercise, both of which increase the user's rate of metabolizing calories, and both of which can thus cause weight loss even without a suppressed appetite. *See e.g.,* Albert M. FLEISCHNER, DECLARATION (21 December 2005) at ¶ 9.

2. Appetite Suppression Does Not Always Cause Weight Loss

Similarly, it is possible to suppress appetite without causing weight loss. Apparently, suppressing food intake lowers the body's basal metabolic rate. *See* Albert M. FLEISCHNER, DECLARATION (21 December 2005) at ¶ 10. This response allows the body to maintain a constant weight even with a lower caloric intake. *Id*.

The art of record confirms this. For example, VAN HEERDEN at Example 44 teaches that the appetite suppressant compound fenfluramine has no effect on body weight:

> "fenfluramine (7.5 mg/kg) produced statistically significant reductions in food consumption…. No statistically significant effects on water consumption or bodyweight were recorded."

Albert M. FLEISCHNER, DECLARATION (21 December 2005) at ¶ 11 (quoting VAN HERDEN). Similarly, VAN HEERDEN teaches that the compound 3-0-[-ß-D-thevetopyrano-sylcymaropyranosyl]-12ß-0-tigloyloxy-14ß-hydroxy-14-pregn-50-en-20-one suppresses appetite, yet has no effect on body weight:

> "Sample 3 (active moiety) produced statistically significant reductions in food consumption at an oral dose of 5.0 mg/kg. No statistically significant effects on body weights were produced by the active moiety."

Id. at ¶ 12. VAN HEERDEN thus confirms that appetite suppression does not cause weight loss; to the contrary, appetite suppression may have no effect on body weight. *Id.* at ¶¶ 8 to 46.

*3. Appetite Suppression May Cause Weight **Gain***

Appetite suppression does not invariably cause weight loss. To the contrary, it may cause weight ***gain***.

John BLUNDELL, 2 TRENDS IN PHARMACOL. SCI., 147 (1991), says that the most widely-used appetite suppressant in the world can also cause weight gain:

> "Food is an excellent anorectic agent which is known to reduce hunger and to suppress eating for some time after administration. However, one major disadvantageous side-effect of food as an appetite suppressant is that it is also known to lead to weight gain."

BLUNDELL thus concludes that appetite suppression is not sufficient for weight control; to the contrary, BLUNDELL concludes, "The development of safe and effective anti-obesity drugs involves far more than control of appetite; it includes *inter alia* the intention to alter processes concerned with energy expenditure, fat synthesis and storage, and the digestion and absorption of nutrients."

An example of a compound which suppresses appetite, yet causes weight gain, is 3-0-[-ß-D-thevetopyrano-sylcymaropyranosyl]-12ß-0-tigloyloxy-14ß-hydroxy-14-pregn-50-en-20-one, the active moiety studied in VAN HEERDEN. VAN HEERDEN's data shows that this compound suppresses appetite transiently, then stimulates appetite. Albert M. FLEISCHNER, DECLARATION (21 December 2005) at ¶¶ 17 *et seq*. Apparently, the initial appetite suppression slows the user's metabolic rate, so the later appetite stimulation causes a marked *weight gain*. *Id*.

4. The Patent Office Recognizes That Appetite Suppression And Weight Loss Are Patentably Distinct Phenomena

One of skill in the art recognizes that appetite suppression and weight control are distinct phenomena. The Patent Office also recognizes this distinction. This is shown in the Office's processing of various third-party patents.

For example, Robert D. SOFIA, U.S. Patent No. 5,290,808 claims a method of administering 2-phenyl-1,3-propanediol dicarbamate to suppress

appetite. In contrast, Walter E. KOZACHUK, U.S. Patent Nos. 5,942,540 and 6,515,019, claims the use of 2-phenyl-1,3-propanediol dicarbamate to treat obesity. Saliently, during prosecution of the '540 and '019 obesity patents, the Examiner cited the '808 appetite suppression patent. The Office's ultimate decision to allow the obesity patents shows that the Office recognizes that one of skill in the art would know that treating obesity and suppressing appetite are not only different, but in fact are patentably distinct.

To render obvious, the prior art must teach each and every element of the claims at issue. *In re Royka*, 490 F.2d 981 (C.C.P.A. 1974). In the immediate case, however, the references of record – alone nor combined – fail to teach every element of the claims.

C. VAN HEERDEN Fails To Teach Every Claim Element Of Claims 1, 3, 19 And 35

To establish *prima facie* obviousness, the prior art must teach each and every claim limitation. *E.g., In re Royka*, 490 F.2d 981 (C.C.P.A., 1974). In the immediate case, VAN HEERDEN fails to teach a number of claim limitations. To the contrary, VAN HEERDEN - alone nor combined - fails to teach each and every claim element of Claims 1, 3, 19 nor 35.

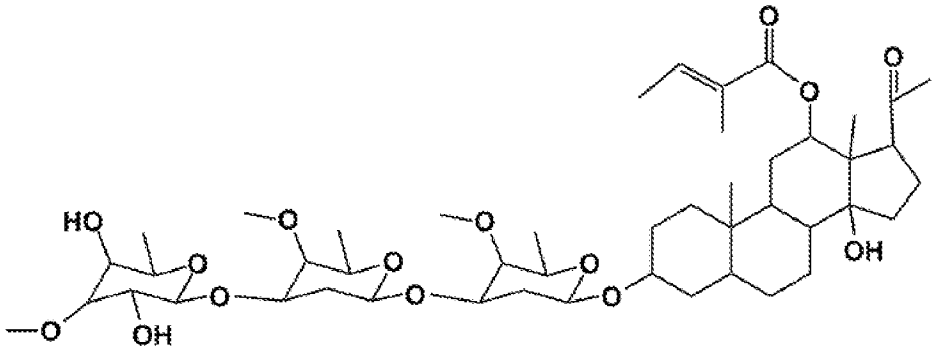
1. VAN HEERDEN Teaches That 3-0-[-ß-D-thevetopyrano-sylcymaropyranosyl]-12ß-0-

tigloyloxy-14ß-hydroxy-14-pregn-50-en-20-one Causes Weight Gain

To render the claims obvious, the prior art must teach a reasonable expectation of success. *E.g., In re Rinehart*, 531 F.2d 1048 (C.C.P.A., 1976). In evaluating this, one must consider testimony which explains why the prior art fails to provide a reasonable expectation of success. *Amgen, Inc. v. Chugai Pharma. Co.*, 927 F.2d 1200, 1207-08 (Fed. Cir., 1991), *certiorari denied*, 502 U.S. 856.

In the immediate case, the Inventor has testified at length and in detail about how VAN HEERDEN teaches a reasonable expectation not of success, but of *failure*.

In the immediate case, the claims are drawn to a method of weight loss using *Hoodia gordonii*. In contrast, VAN HEERDEN teaches that 3-0-[-ß-D-thevetopyrano- sylcymaropyranosyl]-12ß-0-tigloyloxy-14ß-hydroxy-14-pregn-50-en-20-one, (*see illustration*) a compound which occurs naturally in



Hoodia gordonii, can cause *weight gain*. *See* Albert M. FLEISCHNER, DECLARATION (21 December 2005) at ¶¶ 17 *et seq*. While VAN HEERDEN does not address the use of *Hoodia gordonii* itself, VAN HEERDEN implies that the

administration of *Hoodia gordonii* may entail the administration of a weight-gain inducing amount of 3-0-[-ß-D-thevetopyrano-sylcymaropyranosyl]-12ß-0-tigloyloxy-14ß-hydroxy-14-pregn-50-en-20-one. VAN HEERDEN thus implies that the administration of *Hoodia gordonii* may cause weight gain.

This result is the opposite to the Inventor's result, and the opposite to the use claimed. VAN HEERDEN thus teaches a reasonable expectation of *failure*. VAN HEERDEN thus teaches away from the claimed invention.

2. VAN HEERDEN Teaches the use of 3-0-[-ß-D-thevetopyranosylcymaro-pyranosyl]-12ß-0-tigloyloxy-14ß-hydroxy-14-pregn-50-en-20-one, not Hoodia gordonii

VAN HEERDEN teaches the use of 3-0-[-ß-D-thevetopyrano-sylcymaropyranosyl]-12ß-0-tigloyloxy-14ß-hydroxy-14-pregn-50-en-20-one. *See* Albert M. FLEISCHNER, DECLARATION (21 December 2005) at ¶¶ 42 to 43. VAN HEERDEN does not teach nor claim a use of a plant. *Id*.

3. VAN HEERDEN Fails to Teach the Administration Regimen of Claim 2, nor of claim 35.

VAN HEERDEN fails to teach the administration regimen of Claim 2, nor of claim 35.

4. VAN HEERDEN Fails to Teach the Combination of Claim 3 Nor Claim 19

VAN HEERDEN fails to teach the combination of *Hoodia* with glucosamine, nor a stimulant, nor with any other claimed ingredient.

5. VAN HEERDEN Fails to Render Obvious the Claimed invention

VAN HEERDEN fails to render obvious the claimed invention because VAN HEERDEN fails to teach each element of the claims and because VAN HEERDEN teaches away from the claimed invention.

D. BARNETT and KAHN Fail to Teach Weight Loss

Anthony BARNETT, *In Africa the Hoodia Cactus Keeps Men Alive*, THE OBSERVER (17 June 2001) and Tamar KAHN, *Prickly Dispute Finally Laid To Rest*, BUSINESS DAY (JOHANNESBURG) (22 March 2002) each teach that *Hoodia gordonii* causes transient appetite suppression. *See* Albert M. Fleischner, Declaration (13 June 2006) at ¶¶ 32 to 33.

While each teaches appetite suppression, neither teaches that *Hoodia gordonii* can cause weight loss. *Id*. Neither teaches the claimed administration periods. Neither teaches the combination of *Hoodia* with glucosamine, nor a stimulant, nor with any other claimed ingredient.

E. HABECK Refuses To Say Whether Or Not 3-0-[-ß-D-thevetopyrano-sylcymaropyranosyl]-12ß-0-tigloyloxy-14ß-hydroxy-14-pregn-50-en-20-one Causes Weight Loss

Martina HABECK, *A Succulent Cure To End Obesity*, 7 DRUG DISCOV. TODAY 280 (March, 2002) summarizes a corporate news release issued by Phytopharm, Ltd. of the United Kingdom. HABECK teaches that a study was done of two groups of obese people. One group was given 3-0-[-ß-D-thevetopyrano-sylcymaropyranosyl]-12ß-0-tigloyloxy-14ß-hydroxy-14-pregn-50-en-20-one; the other (control) group was not. Both groups were then confined for 15 days in prison-like conditions. *See* Albert M. Fleischner, Declaration (13 June 2006) at ¶¶ 25-26.

After 15 days, the group given 3-0-[-ß-D-thevetopyrano-sylcymaropyranosyl]-12ß-0-tigloyloxy-14ß-hydroxy-14-pregn-50-en-20-one had reduced their body fat content by 1 kilogram. *Id*. HABECK fails to say, however, how much body fat the control group lost. *Id*. at ¶¶ 27-30. To the contrary, HABECK specifically withheld the results of the control group. *Id*.

HABECK therefore fails to inform one of skill in the art about whether the body fat change was due to, for example, the prison-like conditions under which test subjects were held, or the bad quality of food which they were given. This document therefore fails to inform one of skill in the art whether the change in body fat was caused by 3-0-[-ß-D-thevetopyrano-sylcymaropyranosyl]-

12ß-0-tigloyloxy- 14ß-hydroxy-14-pregn-50-en-20-one, or by some other factor. *Id*.

Further, concealing control group results is unusual. *Id*. It implies that the experiment produced adverse data. *Id*. Thus, one of skill in the art would read HABECK to imply that 3-0-[-ß-D-thevetopyrano-sylcymaropyranosyl]-12ß-0-tigloyloxy-14ß-hydroxy-14-pregn-50-en-20-one was not effective to reduce body fat. *Id*.

1. HABECK Fails to Teach the Administration Regimen of Claim 2, nor of claim 35.

HABECK Fails to Teach the Administration Regimen of Claim 2, nor of claim 35.

2. HABECK Fails to Teach the Combination of Claim 3 Nor Claim 19

HABECK fails to teach the combination of *Hoodia* with glucosamine nor a stimulant, nor with any other ingredient.

3. HABECK Is an Invitation To Experiment

Propossing that research be done, without providing an assurance of success, is a mere "invitation to experiment." *See Elan Pharma., Inc. v. Mayo Found. Med. Educ. And Res.,* 304 F.3d 1221, 1228 (Fed. Cir. 2002.

For example, in *Adang v. Fischoff*, 286 F.3d 1346, 1352 (Fed. Cir., 2002) the prior art reference taught that "the analysis was ongoing." The Federal Circuit found that where the prior art itself taught that the analysis was ongoing, rather than complete, the prior art merely provided an invitation to invent, not an enabling disclosure sufficient to render obvious the claims at issue.

Similarly, in *Hybritech Inc. v Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir., 1986), the Federal Circuit found that numerous prior art predictions of future success merely amounted to a collection of invitations to invent, rather than a disclosure enabling the practice of the claimed invention.[4]

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[4] *Hybritech* provides a number of examples of prior art references which invite experimentation. The inventor claimed the use of monospecific antibodies in immunodiagnostic testing. The references of record art taught, *inter alia*:

- ✓ "The use of monospecific antibodies in immunodiagnostic testing is obvious,"
- ✓ "The specificity and uniformity of monoclonal antibodies should markedly improve diagnostic accuracy,"
- ✓ "An essentially unlimited supply of monoclonal antibodies, precisely defined according to amount and affinity, will lead to major improvements and innovations in immuno medicine techniques."
- ✓ "For immunodiagnostics, monoclonal antibodies will improve performance, reduce costs and open up types of immunological testing. More obvious advances will include: antibodies for use with … enzyme … immunoassays,"
- ✓ "Combined with the exploitation of the in vitro hybridoma techniques of antibody production … with which large quantities of monospecific

The court noted that because the prior art failed to provide an assurance of success, it did not render the claimed invention obvious.

In the instant case, HABECK teaches that it is still "early days" in doing research in this area. Albert M. Fleischner, Declaration (13 June 2006) at ¶ 31. HABECK teaches that for a useful invention to be made, further experimentation needs to be done to determine whether the effect is consistent over longer periods of time. *Id*. HABECK specifically teaches that for a useful invention to be made, further experimentation needs to be done to "take a closer look at the dosing interval." *Id*.

HABECK thus provides an invitation to experiment, with no assurance of success. *Id*.

F. TULP Provides an Invitation To Experiment

TULP (2001) fails to render the claims obvious because TULP (2001) presents results which are not indicative of efficacy in humans.

> antibodies can be produced, the emergence of simple and reliable assay procedures … is within sight."

See Hybritech Inc. v Monoclonal Antibodies, Inc., 623 F.Supp. 1344, 1355 (N.D.Cal., 1985). The Federal Circuit found such teachings to be mere invitations to do research. *Hybritech Inc. v Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir., 1986).

1. TULP's Results With LA//Ntul//-cp Mutant Laboratory Rats Do Not Predict Human Efficacy

TULP (2001) uses LA/Ntul//-cp laboratory rats. Albert M. Fleischner, Declaration (13 June 2006) at ¶¶ 17 to 22. LA/Ntul//-cp laboratory rats have a number of mutations. These mutations cause impaired carbohydrate tolerance, hyperamylinemia, hypertrigliceridimia and hypercholesterolemia, and an impaired capacity for non-shivering thermogenesis and energy expenditure. *Id*. These rats display morbid, early-onset obesity. *Id*. at ¶ 19.

TULP teaches that this kind of rat can lose weight if administered *Hoodia gordonii* for short periods. This result, however, fails to provide any assurance of success in humans because LA/Ntul//-cp mutants are so different from normal rats (and from normal human beings). Albert M. Fleischner, Declaration (13 June 2006) at ¶ 20 to 23. TULP's results do not provide any assurance of success in humans. Because TULP fails to teach an assurance of success, TULP provides a mere invitation to experiment.[5] *See Elan Pharma., Inc. v. Mayo Found. Med. Educ. And Res., 304 F.3d 1221, 1228 (Fed. Cir. 2002)*; *Adang v. Fischoff*,

[5] TULP (2001) also says that *Hoodia* extract changes food intake. Albert M. Fleischner, Declaration (13 June 2006) at ¶¶ 10-16. TULP (2001), however, fails to say *how much* food intake changes. *Id*. This leaves one to speculate whether his *Hoodia* extract causes a net decrease or ***a net increase*** in food intake. *Id*. at ¶ 15.

286 F.3d 1346, 1352 (Fed. Cir., 2002); *Hybritech Inc. v Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1380 (Fed. Cir., 1986).

2. TULP Fails To Provide A Motivation To Modify Its Disclosure To Create The Combination Of Claims 3 And 19, Nor The Administration Regimens

The Examiner says that the claims differ from TULP in two aspects: TULP fails to teach the combination of claims 3 and 19, and TULP fails to teach the administration regimens of claims 2 and 35.

a) The Art Of Record Fails To Suggest the Administration Periods Of Claims 2 and 35

A *prima facie* case of obviousness requires identification in the prior art of record of some suggestion to modify the prior art to reach the claimed invention. *In re Lee*, 277 F.3d 1338, 1344 (Fed.Cir., 2002) (there must be some "hint or suggestion in a particular reference").

In the immediate case, the OFFICE ACTION fails to identify any suggestion in the art of record to make the claimed combinations or the claimed administration regimens. The OFFICE ACTION simply takes judicial notice that "determining appropriate, suitable time periods and intervals … is deemed merely a matter of judicious selection and routine optimization."

Applicant respectfully disagrees because HABECK, at page 2, expressly teaches that determining appropriate administration intervals is neither routine nor predictable. *See* Albert M. FLEISCHNER, Declaration (13 June 2006) at ¶ 31.

Furthermore, the art of record teaches that at whatever interval, the claimed invention would not work. For example, VAN HEERDEN at Figures 5 and 6 shows that administration would precipitate weight ***gain***, not weight loss. *See* Albert M. Fleischner, Declaration (30 Dec 2005) at ¶ 17 *et seq*. Similarly, HABECK teaches that administration does not produce weight ***loss***, and may produce weight ***gain***. *See* Albert M. Fleischner, Declaration (13 June 2006) at ¶¶ 15, 28-30, 35-36.

b) The Art Of Record Fails to Suggest the Combination of Claims 3 and 19

The OFFICE ACTION correctly notes that it is *prima facie* obvious to combine ingredients which are each individually recognized as effective for the same use. The OFFICE ACTION then alleges that *Hoodia gordonii* has a "well recognized activity in promoting weight loss" in humans.

This allegation is not correct. To the contrary, VAN HEERDEN at Figures 5 and 6 teaches that 3-0-[-ß-D-thevetopyrano-sylcymaropyranosyl]-12ß-0-tigloyloxy-14ß-hydroxy-14-pregn-50-en-20-one has "well recognized activity" in

promoting weight ***gain*** in humans. *See* Albert M. Fleischner, Declaration (30 Dec 2005) at ¶ 17 *et seq*.

Similarly, HABECK at 1 teaches that 3-0-[-ß-D-thevetopyrano-sylcymaropyranosyl]-12ß-0-tigloyloxy-14ß-hydroxy-14-pregn-50-en-20-one has no "well recognized activity"; to the contrary, it might promote weight gain in humans, but the relevant data has been withheld from the public. *See* Albert M. Fleischner, Declaration (13 June 2006) at ¶¶ 15, 30, 34-36.

Thus, it would not have been obvious to combine *Hoodia gordonii* with a stimulant, nor with glucosamine.

IV. THE CLAIMED INVENTION SHOWS SECONDARY INDICIA OF NON-OBVIOUSNESS

The claimed invention has several secondary indicia of non-obviousness. These include A. unexpectedly successful results, B. achieving a new and different function, and C. widespread copying by competitors.

A. The Inventor has achieved unexpected success

Tthe inventor has shown that *Hoodia gordonii* is effective for weight loss. *See* Albert M. FLEISCHNER, DECLARATION (21 December 2005) at ¶¶ 47 to 56, and the Exhibits (clinical trial results) appended to that DECLARATION.

The inventor's results would not have been expected by one of skill in the art at the time the inventor made his invention. *Id*. at ¶ 57. Rather, VAN HEERDEN at Figures 5 and 6 teaches that 3-0-[-ß-D-thevetopyrano-sylcymaropyranosyl]-12ß-0-tigloyloxy-14ß-hydroxy-14-pregn-50-en-20-one causes weight gain.

There is a nexus between the inventor's scientific results and the pending patent claims, because the Inventor's actual clinical testing results discussed in his 2005 Declaration would be considered by one of skill in the art to have probative value in showing that the pending patent claims are both enabled and non-obvious. *Id*. at ¶ 58 to 59.

B. The inventor has achieved a new or different function

While not required for non-obviousness, achieving a new or different function indicates the claimed invention is non-obvious. *See Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, *rehearing denied*, 426 U.S. 955 (1976); *Anderson's Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969).

In the immediate case, the inventor has achieved a function which is not only different from the prior art, but the direct opposite of it. The prior art teaches that 3-0-[-ß-D-thevetopyrano-sylcymaropyranosyl]-12ß-0-tigloyloxy-14ß-

hydroxy-14-pregn-50-en-20-one increases body mass. In contrast, the Inventor claims methods to *decrease* body mass using *Hoodia gordonii* itself.

The claimed invention is non- obvious because the Inventor has achieved a function different than that taught by the prior art.

C. The claimed invention is being widely copied

Widespread copying is a secondary indicator of non-obviousness. *See Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675 (Fed. Cir., 1988).

In the immediate case, the claimed invention is being widely copied. This is shown in two places in the record.

First, quite soon after the Applicant began offering for sale its TrimSpa® brand *Hoodia gordonii* weight control product, competitors began selling slavish copies of it. These copies, sold as TrimSmart™, TrimClub™ and HoodiaSpa™, copied the original TrimSpa® product, the TrimSpa® formula, and used trade marks and trade dress deceptively similar to the original TrimSpa® packaging. *See* PETITION TO MAKE EXAMINATION SPECIAL PURSUANT TO M.P.E.P. § 708.02 (II) (6 July 2005). On reviewing this evidence, the Office agreed that it shows unauthorized copying. *See* ORDER GRANTING PETITION TO MAKE EXAMINATION SPECIAL (2 August 2005).

Second, since its commercial launch, Applicant's TrimSpa® brand *Hoodia gordonii* weight control product has enjoyed significant and continued commercial success. This success has, unfortunately, prompted additional copying, copying which is not merely widespread, but endemic.

For example, with the Google™ search engine, an internet search made on 7 May 2006 and using the search term "hoodia" identified a large number of sources advertising *Hoodia* weight loss products for sale in The United States. These competitors include www.hoodoba.com, www.weightlossguide.com, www.h57.com, www.hoodithin.com and www.phenterlean.com. *See* INFORMATION DISCLOSURE STATEMENT (8 May 2006). While these products no longer copy Applicant's TrimSpa® trade mark, they continue to copy the Inventor's daimed invention. On information and belief, each of these products was made after the TrimSpa® product achieved commercial success, and each of these products appears specifically designed to pirate the claimed invention.

Applicant concedes that none of these competitors appears at present to be particularly large; to the contrary, they appear to be quite small, little more than individuals operating email spam software out of a personal residence. Nonetheless, "widespread copying" does not require the copier be large nor well-financed. This evidence of widespread copying therefore indicates that the

claimed invention is non-obvious. *See Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675 (Fed. Cir., 1988).

V. CONCLUSION

The OFFICE ACTION fails to state a *prima facie* case to reject any claim. Applicant therefore respectfully requests withdraw of all rejections and prompt allowance of its claims.

Respectfully Submitted on behalf of the Applicant by its attorneys,
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A. CLAIMS APPENDIX

1. A method of body weight reduction, comprising administering to a human in need thereof a body weight reducing amount of *hoodia gordonii* at least once every about 48 hours, for at least about 45 days.

2. The method of claim 1, said *hoodia gordonii* administered at least three times every 24 hours.

3. The method of claim 1, further comprising administering a second compound selected from the group consisting of a stimulant and glucosamine, said second compound administered in an amount sufficient to lessen the amount of *hoodia gordonii* required for body weight reduction.

4. The method of claim 3, said second compound comprising a stimulant and glucosamine.

5. The method of claim 4, said *hoodia gordonii* present in an amount from about 5 to about 200 milligrams per day, said glucosamine present in an amount from 0 to about 200 milligrams per day, and said stimulant comprising caffeine present in an amount from 0 to about 250 milligrams per day.

6. The method of claim 3, wherein said *hoodia gordonii* consists essentially of the whole *hoodia gordonii* plant, less the roots.

7. The method of claim 2, comprising administering from about 5 to about 200 milligrams of *hoodia gordonii*, together with from about 50 to about 200 micrograms of chromium, from about 10 to about 50 micrograms of vanadium, 0 to about 400 milligrams of glucomannan, from about 25 to about 200 milligrams of sodium carboxymethylcellulose, 0 to about 15 milligrams of citrus naringinine, 0 to about 200 milligrams of glucosamine, 0 to about 500 milligrams of cocoa PEA standardized extract, and 0 to about 250 milligrams of green tea extract.

8. to 16. (cancelled)

17. The method of claim 2, comprising administering from about 5 to about 200 milligrams of *hoodia gordonii*, together with from about 50 to about 200 micrograms of chromium, from about 10 to about 50 micrograms of vanadium, from 0 to about 200 milligrams of sodium carboxymethylcellulose, 0 to about 15 milligrams of citrus naringinine, 0 to about 100 milligrams of glucosamine, 0 to about 500 milligrams of cocoa PEA standardized extract, 0 to about 250 milligrams of green tea extract, from about 10 to about 200 milligrams of 3-acetyl-7-oxo-dehydroepiandrosterone, and 0 to about 15 milligram of ma huang .

18. The method of claim 2, comprising administering from about 5 to about 200 milligrams of *hoodia gordonii*, together with from about 50 to about 200 micrograms of chromium, from about 10 to about 50 micrograms of vanadium,

from 0 to about 200 milligrams of sodium carboxymethylcellulose, 0 to about 15 milligrams of citrus naringinine, 0 to about 500 milligrams of cocoa PEA standardized extract, 0 to about 250 milligrams of green tea extract, and 0 to about 250 milligrams of *Coleus Forskohlii*.

19. A composition of matter for body weight reduction, comprising a body weight reducing amount of *hoodia gordonii* together with a second compound selected from the group consisting of a stimulant and glucosamine, said second compound in an amount sufficient to lessen the amount of *hoodia gordonii* required for body weight reduction.

20. The composition of claim 19, said second compound comprising a stimulant and glucosamine.

21. The composition of claim 19, said *hoodia gordonii* present in an amount from about 5 to about 200 milligrams, said glucosamine present in an amount from 0 to about 200 milligrams, and said stimulant comprising caffeine present in an amount from 0 to about 250 milligrams.

22. The composition of claim 19, wherein said *hoodia gordonii* consists essentially of the whole *hoodia gordonii* plant, less the roots.

23. The composition of claim 19, said *hoodia gordonii* comprising from about 5 to about 200 milligrams of *hoodia gordonii* and said stimulant comprising green tea extract.

24. The composition of claim 23, said *hoodia gordonii* comprising about 100 milligrams of *hoodia gordonii* and said stimulant comprising about 250 milligrams of green tea extract.

25. The composition of claim 24, further comprising about 75 micrograms of chromium, about 15 micrograms of vanadium, and about 100 milligrams of sodium carboxymethylcellulose, and about 7.5 milligrams of citrus naringinine.

26. The composition of claim 19, said *hoodia gordonii* comprising about 100 milligrams of *hoodia gordonii* and said stimulant comprising cocoa PEA standardized extract.

27. (canceled)

28. The composition of claim 19, said *hoodia gordonii* comprising about 150 milligrams of *hoodia gordonii* and said second compound comprising glucosamine.

29. The composition of claim 28, further comprising cocoa PEA standardized extract, and green tea extract.

30. The composition of claim 23, said *hoodia gordonii* comprising about 7.5 milligrams of *hoodia gordonii* , said stimulant further comprising cocoa PEA standardized extract.

31. The composition of claim 23, said *hoodia gordonii* comprising about 100 milligrams of *hoodia gordonii* and said second compound comprising about 75 micrograms of chromium, about 15 micrograms of vanadium, and about 50 milligrams of sodium carboxymethylcellulose; said composition further comprising about 200 milligrams of glucomannan, about 5 milligrams of citrus naringinine, about 50 milligrams of glucosamine, about 162.5 milligrams of cocoa PEA standardized extract, and about 125 milligrams of green tea extract.

32. The composition of claim 30, said stimulant comprising about 162.5 milligrams of cocoa PEA standardized extract and about 125 milligrams of green tea extract.

33. The composition of claim 19, said stimulant comprising *ma huang*.

34. The composition of claim 19, further comprising *Coleus Forskohlii*.

35. A method of body weight reduction, comprising administering to a human in need thereof *hoodia gordonii* in an amount sufficient to suppress the appetite after said administration, said administration repeated a plurality of times, each one of

said times occurring before said *hoodia gordonii* causes an appetite stimulating effect.

36. The method of claim 35, said *hoodia gordonii* administered at least three times every 24 hours.

37. The method of claim 35, further comprising administering a second compound selected from the group consisting of a stimulant and glucosamine, said second compound administered in an amount sufficient to lessen the amount of *hoodia gordonii* required for body weight reduction.

38. The method of claim 37, said second compound comprising a stimulant and glucosamine.

39. The method of claim 38, said *hoodia gordonii* present in an amount from about 5 to about 200 milligrams per day, said glucosamine present in an amount from 0 to about 200 milligrams per day, and said stimulant comprising caffeine present in an amount from 0 to about 250 milligrams per day.

40. The method of claim 37, wherein said *hoodia gordonii* consists essentially of the whole *hoodia gordonii* plant, less the roots.

B. EVIDENCE APPENDIX

Enclosed find the two Rule 132 Declarations of record in this case. All evidence relied on has previously been entered into the record before filing of the NOTICE OF APPEAL, as shown on the table below. Physical copies of this evidence is not included here because the Board has copies of this evidence already, via the PAIR system.

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Pieter VAN DER WALT, *The Kalahari and Its Plants* (1999)	13 June 2006
Fanie Retief VAN HEERDEN *et al.*, *Pharmaceutical Compositions Having Appetite Suppressant Activity*, U.S. Letters Patent No. 6,376,657	23 Oct 2003
Ben-Erik VAN WYK, *People's Plants* (2000)	13 June 2006
www.Weightlossguide.com website	9 May 2006

C. RELATED PROCEEDINGS APPENDIX

None.